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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,980	02/13/2001	Douglas A. Holtzman	MPI2000-544OMNI	2000

7590 01/17/2003

Intellectual Property Group
MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER
MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/782,980	Holtzman et al.
Examiner	**Art Unit**
Maryam Monshipouri	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-71 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-7, 12, 18 and 26-27, drawn to isolated DNA sequences encoding Interleukin Ten Associated Locus Yang (ITALY) polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.
2. Claims 1-7, 12, 18 and 28-29, drawn to isolated DNA sequences encoding lysyl oxidase related protein-2 (Lor-2) polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.
3. Claims 1-7, 12, 18 and 30-35, drawn to isolated DNA sequences encoding murine STRIFE1 polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.
4. Claims 1-7, 12, 18 and 36-41, drawn to isolated DNA sequences encoding human TRASH polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.
5. Claims 1-7, 12, 18 and 42-43, drawn to isolated DNA sequences encoding human BDSF-1 polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.

6. Claims 1-7, 12, 18 and 44-46, drawn to isolated DNA sequences encoding Murine BDSF-1 polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.

7. Claims 1-7, 12, 18 and 47-48 drawn to isolated DNA sequences encoding Human LRSG-1 polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.

8. Claims 1-7, 12, 18 and 49-50 drawn to isolated DNA sequences encoding Murine LRSG-1 polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.

9. Claims 1-7, 12, 18 and 51-54 drawn to isolated DNA sequences encoding Human STMST-1 polypeptides, host cells , and kits comprising said sequences and methods of expressing said sequences, classified in class 435, subclass 69.1.

10. Claims 8-10, 55-56, drawn to said ITALY polypeptides, classified in class 530, subclass 350.

11. Claims 8-10, 57, drawn to human Lor-2 polypeptide, classified in class 530, subclass 350.

12. Claims 8-10, 58-59, drawn to murine STRIFE1, classified in class 530, subclass 350.

13. Claims 8-10, 60-63, drawn to human TRASH, classified in class 530, subclass 350.

14. Claim 8-10, 64-65, drawn to human BDSF-1, classified in class 530, subclass 350.

15. Claim 8-10, 66-67, drawn to murine BDSF-1, classified in class 530, subclass 350.

16. Claim 8-10, 68, drawn to human LRSG-1, classified in class 530, subclass 350.

17. Claim 8-10, 69, drawn to murine LRSG-1, classified in class 530, subclass 350.

18. Claim 8-10, 70-71, drawn to human STMST1, classified in class 530, subclass 350. 350 -

19. Claims 11, 13-15, 23-25, drawn to antibodies which bind said polypeptides, methods of making and methods of using said antibodies, classified in class 435, subclass 7.1.

20. Claims 16-17, drawn to methods of use of said DNA sequences in a hybridization assay, classified in class 435, subclass 6.

21. Claims 19-20 and 22, drawn to method of identifying modulators of said polypeptides, classified in class 436, subclass 86 .

22. Claim 21, drawn to methods of modulating the activity of said polypeptides, classified in class 514, subclass 12.

The DNA of Groups 1-9, the polypeptides of Groups 10-18 and the antibdoies of Group 19 are patentably distinct each from the other because each product is directed to an unrelated chemical structure and function.

Each of inventions of Groups 1-9 and Group 20 invention are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of DNA inventions of Groups 1-9 may be used for recombinant expression of respective polypeptides which are totally different methods than that of Group 20.

Each of inventions of Groups 1-9 are unrelated to any of the methods of Groups 21-22 because said products are neither made not used by any of said methods.

Each of inventions of Groups 10-18 and each of the methods of Groups 21-22 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the polypeptides of Groups 10-18 may be used for respective antibody preparation which is a totally different method than any of those of Groups 21-22.

The antibodies of Group 19 are unrelated to any of the methods of Groups 20-22 because said products are neither made nor used by any of saud methods.

Each of the polypeptides of Groups 10-18 are unrelated to the method of Group 20 because said products are neither made nor used by said method.

Methods of Groups 20-22 are patentably distinct each from the other because each method has different steps and different end-points.

Applicant is also reminded that inventions of Groups **19-22 are generic to plurality of inventions**, namely ITALY polypeptides, Lor-2 polypeptides, murine STRIFE1, human TRASH, human BDSF-1, murine BDSF-1 and human STMST1 which for simplification purposes were kept rejoined. In case applicant decides to elect any of inventions of Groups 20-22 further election of a single polypeptide is necessary.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Primary Examiner